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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/479,467	01/06/00	STERNBERG	P 18021-2919

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EXAMINER

PARAS JR, P

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 08/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/479,467

Applicant(s)

STERNBERG ET AL.

Examiner

Peter Paras, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-92 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-92 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

Specification

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). On pages 60-61 there are 2 sets of claims 17-19 (meaning that there are 3 additional claims in the instant application). The second set of claims 17-19 and the remaining claims were renumbered 20-92. Please refer to the revised numbering of claims with respect to the instant office action.

Claims 1-92 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3, 5, 7, 9-11, 15-17, 21-22, 25-32, 41-42, 49, 74-77, 82-84, drawn to a nucleic acid sequence encoding a nematode Lov-1 gene, a mutated form of same Lov-1 sequence, a vector encoding same Lov-1 nucleic acid sequence, a transgenic nematode comprising same Lov-1 nucleic acid sequence, a transgenic nematode comprising same mutated Lov-1 nucleic acid sequence, a method of identifying genes classified in classes 536, 435, 800, subclasses 23.1, 320.1, 13.

- II. Claims 2, 4, 6, 8, 12-14, 18-20, 23-24, 33-40, 43-44, 74-77, 81-83, 85, and 92, drawn to a nucleic acid sequence encoding nematode PKD-2, a mutated form of same nucleic acid sequence, a vector encoding same PKD-2 nucleic acid sequence, a transgenic nematode comprising same PKD-2 nucleic acid sequence, a transgenic nematode comprising same mutated PKD-2 nucleic acid sequence, a method of identifying genes classified in classes 536, 435, and 800, subclasses 23.1, 320.1, and 13.
- III. Claims 45-46, drawn to drawn to an isolated LOV-1 polypeptide, classified in class 530, subclass 350.
- IV. Claims 47-48, drawn to an isolated PDK-2 polypeptide, classified in class 530, subclass 350.
- V. Claim 50, drawn to a LOV-1-PDK-2 protein complex, classified in class 530, subclass 402.
- VI. Claims 51-55, drawn to a method of mutating LOV-1 or PKD-2 genes in a nematode, classified in class 435, subclass 441.
- VII. Claims 56-63, drawn to a method of treating a nematode with a compound that alters mating behavior, and method for identifying compounds that can alter mating behavior, classified in class 435, subclass 441.
- VIII. Claims 64-66, 68-70, 72-73, and 91, drawn to a method for identifying genes which are part of the disease pathway of autosomal polycystic kidney disease, classified in class 435, subclass 6.

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- IX. Claims 67 and 71, drawn to a method for identifying compounds that are potentially therapeutic for treatment of polycystic kidney disease, classified in class 435, subclass 7.
- X. Claims 78-87, drawn to a method of screening nematodes using bacteria, classified in classes 435 and 435 subclasses 441 and 7.2.
- XI. Claims 88-89, drawn to a mutant strain of nematode comprising a mutated LOV-1 gene, classified in class 800, subclass 8.
- XII. Claims 88 and 90, drawn to a mutant strain of nematode comprising a mutated PDK-2 gene, classified in class 800, subclass 8.

Inventions I and II are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid sequence of invention I is a gene associated with mating behavior. The nucleic acid of invention II is a gene associated with polycystic kidney disease. Because these inventions are distinct for the reasons given above and the search required for invention I is not required for invention II, restriction for examination purposes as indicated is proper.

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Inventions I-II and III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The nucleic acid molecule of invention I can be used to transform somatic cells *in vitro* and as a probe in a hybridization assay. The polypeptide of invention III can be used as an antigen to generate antibodies in a host. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions I-II and VI-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The nucleic acid molecule of invention I can be used to transform somatic cells *in vitro* and as a probe in a hybridization assay. The methods of inventions VI-X can be used with materially different products. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions I-II and XI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

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modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The nucleic acid molecules of invention I can be used to transform somatic cells *in vitro* and as a probe in a hybridization assay. The mutant strain of nematode of invention XI can be used to test potentially therapeutic compounds *in vivo*. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions III, IV, and V are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the protein of invention III is a LOV-1 polypeptide associated with mating behavior. The protein of invention IV is a PKD-2 polypeptide associated with polycystic kidney disease. The complex of invention V comprises the LOV-1 and PDK-2 polypeptides. Because these inventions are distinct for the reasons given above and separate searches are required for inventions III, IV, and V, restriction for examination purposes as indicated is proper.

Inventions III-V and VI-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

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modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The polypeptide of invention III can be used as an antigen to generate antibodies in an animal. The methods of inventions VI-X can be used with materially different products. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions III-V and XI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The polypeptide of invention III can be used as an antigen to generate antibodies in animal. The mutant strain of nematode of invention XI can be used to test potentially therapeutic compounds *in vivo*. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between groups VI, VII, VIII, IX, and X because their methods appear to constitute patentably distinct inventions, each with a distinct purpose

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and further comprising distinct methodologies and using different products. Because these inventions are distinct for the reasons given above and a separate search is required for each of Groups VI, VII, VIII, IX, and X restriction for examination purposes as indicated is proper.

Inventions VI-X and XI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The mutant strain of nematode of invention XI can be used to test potentially therapeutic agents in vivo. The methods of inventions VI-X can be used with materially different products. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions XI and XII are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the mutant strain of nematode of invention XI comprises a mutant LOV-1 gene. The mutant strain of nematode of invention XII comprises a mutant PKD-2 gene. Because these

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inventions are distinct for the reasons given above and separate searches are required for inventions XI and XII, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Stephanie Seidman on 8/2/00 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Stanton, can be reached at 703-308-2801. The FAX phone number for art unit 1632 is 703-308-0294.

Inquiries of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Peter Paras, Jr.

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P. Paras, Jr.
Patent Examiner
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